

BS

35. The radiating device according to claim 34, wherein the balloon is adapted to be inflated by a second fluid.

BS

43. The radiating device according to claim 11, adapted to contact a cavity that is an organ.

BS

44. The radiating device according to claim 11, adapted to contact a cavity that is a hollow organ.

BS

45. The radiating device according to claim 11, adapted to contact a cavity that is a bladder.

REMARKS

In the pending Office Action, the Examiner rejected claims 1-47 under 35 U.S.C. § 101, as being directed to non-statutory subject matter; rejected claims 1-47 under 35 U.S.C. § 112, second paragraph, for indefiniteness; rejected claims 6-20 and 24-79 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,344,435 issued to Turner et al. in view of U.S. Patent No. 5,084,044 issued to Quint; and rejected claims 21 and 22 under 35 U.S.C. § 103 as being unpatentable over Turner et al. and Quint in view of U.S. Patent No. 4,662,383 issued to Sogowa et al. The Examiner's rejections are traversed and are addressed in the order presented in the Office Action.

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Claims 1-91 are presently pending in this application, including patent claim 1 and newly added claims 2-91. No new matter has been added by virtue of the claim amendments set forth above.

As a preliminary matter, Applicant notes that the Examiner failed to consider in the pending Office Action the Preliminary Amendment filed in this application on June 15, 1998. That Preliminary Amendment included new claims 80-91. For the convenience of the Examiner a copy of the previously filed Preliminary Amendment and a copy of the postcard evidencing receipt by the U.S. Patent and Trademark Office of the Preliminary Amendment are enclosed with this Amendment. Applicant requests consideration of this Preliminary Amendment by the Examiner. If the pending claims are not allowed in response to the instant Amendment, the subsequent Office Action should not be made final because of the non-consideration of the previously-filed Preliminary Amendment.

The Examiner rejected claims 1-47 under 35 U.S.C. § 101. This rejection is traversed and Applicant notes that the recitation of an organ, a cavity, or the bladder in the claims does not positively include these body parts as part of the claimed invention. Nonetheless, to expedite prosecution of this application, Applicant has amended the claims as suggested by the Examiner. Applicant requests reconsideration and withdrawal of this rejection.

The Examiner next rejected claims 1-47 under 35 U.S.C. § 112, second paragraph, for indefiniteness. This rejection is traversed. As set forth in the above claim amendments, Applicant has amended the claims to address the supposed deficiencies pointed out by the Examiner. If the Examiner continues to reject any claim under § 112,

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second paragraph, Applicant requests that the Examiner suggest appropriate claim language for consideration by Applicant. Applicant requests reconsideration and withdrawal of this rejection.

The Examiner next rejected claims 6-20 and 24-79 under 35 U.S.C. § 103 as being unpatentable over the combination of Turner et al. and Quint. This rejection is traversed.

Turner et al. discloses a urethral inserted applicator for hyperthermal treatment of the prostate. Turner et al. teaches that the catheter 18 is inserted in the urethra and includes an energy applicator thereon. According to Turner et al., a tip zone inflatable balloon 76 is used to position the device and is inflated with water or air by connecting tube 60, which extends along the catheter. Col. 14, lines 51-55 and Figs. 3 and 4b. Turner et al. also discloses a separable insulated temperature sensor 20 located at the tip of the insertable lead 24 that is inserted in a flexible tube 22 to monitor the temperatures along the length of the catheter 18. Col. 11, lines 24-30.

Fig. 4a of Turner et al. illustrates that the flexible tube 22, into which the temperature sensor 20 is located, is attached to the exterior of the catheter body 52. Col. 13, lines 64-66. See also col. 19, lines 27-29, explaining Fig. 13 and flexible tube 152 secured to catheter 18 and housing temperature sensor 162. Turner et al. explains that microprocessor 160 is programmed to perform desired calculations to provide an output representative of the heated tissue. Col. 19, lines 32-35.

Turner et al. also discloses that a cooling fluid can be circulated in the catheter 18 in cooling fluid passage 59 and that waste fluid can be drained through central drainage

tube 56. In addition, as explained above, the catheter 18 of Turner et al. includes passage 60 for inflation of balloon 76. Col. 13, line 58 through col. 14 line 14.

As correctly concluded by the Examiner, Turner et al. fails to disclose or suggest temperature sensing devices that are adapted to contact any portion of a cavity, bladder, or organ.

The Examiner relies on Quint to cure the above-noted deficiencies with respect to Turner et al.. However, Applicant submits that there is no suggestion or motivation to combine Turner et al. with Quint in the manner suggested by the Examiner. Further, even if Turner et al. and Quint are properly combinable, the combination fails to disclose or suggest the presently claimed invention.

The Examiner states that Quint "discloses a similar hyperthermia device [as Turner et al.] whereby heat is applied to a hollow organ via contact of an expandable (i.e. balloon) member with the wall of the organ." Applicant disagrees with the Examiner's analysis.

Quint discloses a method of thermal ablation of the uterus where an expandable member is brought into intimate contact with the endometrium of the uterus. Col.3, lines 5-36. In Quint, the expandable member is filled with a volume of heated fluid and is brought into contact with the organ to perform ablation. Col. 5, lines 8-35. Temperature sensors 46 are affixed to the exterior surface of the expandable member 32. Col. 6, lines 8-10. Because the expandable member of Quint contacts the organ, the temperature sensors 46, affixed thereto, contact the organ as well.

In contrast, in Turner et al., a catheter is placed in the urethra adjacent the prostate. Catheter 18 is kept in place with an expandable balloon 18 and includes a fluid

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dry tube for an energy radiator antenna applicator. Electromagnetic energy is supplied to the applicator and the prostate is irradiated. As explained above, the temperature sensor is maintained in a flexible tube that is connected to the catheter. See the Abstract of Turner et al.

There are fundamental differences in operation and design between Turner et al. and Quint precluding the necessary suggestion to combine Turner et al. and Quint in the manner suggested by the Examiner. In Turner et al., the temperature sensors are contained within a tube that is connected to the catheter. And, in Turner et al., there is no direct contact between the heating member and the organ. Quint provides affixed temperature sensors to the expandable device that carries a heated fluid. And, in Quint, there is direct contact between the heating member and the organ.

Clearly, the purpose and effect of the devices and methodologies disclosed in Turner et al. and Quint are very different from one another. Owing to these differences, one of ordinary skill in the art would not modify Turner et al. to place the temperature sensors outside of the catheter. The very different structure and operation of Quint does not suggest this modification.

The Examiner has not pointed to any suggestion or motivation in either Quint or Turner et al. for modifying Turner et al. in the manner suggested by the Examiner. Such a suggestion or motivation is necessary for the Examiner to make a *prima facie* case of obviousness under § 103. *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998).

For this reason, Applicant submits that the rejection based on Turner et al. and Quint is improper and should be withdrawn.

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Applicant also submits, however, that even if Turner et al. and Quint are properly combinable under § 103, these references fail to disclose or suggest the elements of the claimed invention.

Neither Turner et al. nor Quint discloses or suggests that the temperature sensing devices are deflected outward and adapted to contact an organ, bladder, or cavity. Turner et al. teaches only that the temperature sensors are maintained within the catheter. And, Quint discloses that the temperature sensors are affixed to the expandable member. As such, they cannot be deflected outward as recited in each of the independent claims rejected based on the combination of Turner et al. and Quint.

In addition, neither Turner et al. nor Quint disclose or suggest that a fluid is supplied externally of the catheter (Turner et al.) or expandable member (Quint) for treatment. Turner et al. discloses only that a cooling fluid be circulated within the catheter and that waste be vacuumed through the catheter. And Quint discloses only that the fluid be circulated within the expandable member. As a result, no combination of Turner et al. and Quint discloses or suggests providing a fluid to a cavity or organ, as recited in each of the independent claims rejected on the combination of Turner et al. and Quint.

For these reasons as well, Applicant submits that the rejection based on Turner et al. and Quint is improper and requests reconsideration and withdrawal of this rejection.

Applicant also notes that the Examiner failed to address most of the dependent claims rejected on the basis of the combination of Turner et al. and Quint. Applicant does not concede to the propriety of these rejections, but notes that the Examiner has not

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provided a *prima facie* case of obviousness because the Examiner has not shown where the prior art discloses or suggests these various claim elements.

The Examiner also rejected claims 21 and 22 under 35 U.S.C. § 103 as being unpatentable over Turner et al. and Quint in view of Sogawa et al. This rejection is traversed. Applicant notes that Sogawa et al. does not make up for the deficiencies noted with respect to the combination of Turner et al. and Quint. Applicant requests reconsideration and withdrawal of this rejection.

In view of the amendments to the claims and the comments set forth above, Applicant requests allowance of pending claims 1-91 and that this case be passed to issue.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: February 17, 1999

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